

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 24 NOV 2005

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Applicant's or agent's file reference PWO051581	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/US2004/038131	International filing date (day/month/year) 15.11.2004	Priority date (day/month/year) 13.11.2003
International Patent Classification (IPC) or national classification and IPC B65D83/04, B65D75/34		
Applicant MEADWESTVACO CORPORATION et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

- (*sent to the applicant and to the International Bureau*) a total of 13 sheets, as follows:
  - sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
  - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
- (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the International application
- Box No. VIII Certain observations on the international application

Date of submission of the demand 13.09.2005	Date of completion of this report 23.11.2005
Name and mailing address of the International preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Appelt, L Telephone No. +49 89 2399-2570



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/038131

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1, 2, 6-13	as originally filed
3, 3a-3d, 4, 4a, 5	filed with telefax on 18.10.2005

**Claims, Numbers**

1-28	filed with telefax on 18.10.2005
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**Drawings, Sheets**

1/5-5/5	as originally filed
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- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/038131

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes:	Claims	1-28
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-28
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.

PCT/US2004/038131

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents :

- D1: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 05, 14 September 2000 (2000-09-14) & JP 2000 062843 A (TOYAMA CHEM CO LTD), 29 February 2000 (2000-02-29)
- D2: US-A-4 120 400 (KOTYUK ET AL) 17 October 1978 (1978-10-17)
- D3: US-A-5 019 125 (REBNE ET AL) 28 May 1991 (1991-05-28)
- D4: US-B1-6 338 408 (ANDERSON GREGOR J. M) 15 January 2002 (2002-01-15)
- D5: DE 40 01 645 A1 (SIMON, UDO, 8500 NUERNBERG, DE; HAFNER, DIETER, DIPL.-PHYS. DR.RER.NAT) 1 August 1991 (1991-08-01)

**Claim 1**

It is commonly known in the art to place blister packs into trays for the purpose of protecting the blister packs and for providing a means for controlled delivery of the products contained in the blister pack. Such a system is, for example, disclosed in the document D3 (see Fig. 2).

Such systems may also comprise hinged lids and child-resistant closures (see, for example, the document D4, Fig. 1).

It is also known to use guide slots in the blister pack and corresponding guiding means in the tray for controlled movement of the blister pack within the packing tray (see the documents D2 and D5). Another slotted blister pack is, moreover, disclosed in the document D1.

However, none of these documents suggests to provide a child-resistant system by the combination of a hinging cap and a retaining cap, whereby the hinging cap controls access to restricted zones on the blister pack and the retaining cap covers the restricted zones in a first position and allows access to the restricted zones in a second position into which the blister pack has been slid after the hinging cap has been opened.

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.  
PCT/US2004/038131

**Claim 20**

This claim defines a method for packaging items which basically consists in providing a system having the essential features defined in claim 1.

Accordingly, the observation set out above with respect to claim 1 apply in a corresponding manner to claim 20.

**Claim 17**

Claim 17 is directed to a blister pack for use in a packaging system of claim 1. Although the blister packs disclosed in the documents D1, D2 and D5 are also provided with a guiding slot, it is clear that these packs are not adapted to be used with a system according to claim 1. This is in particular due to the fact, that none of these packs includes a chamber free zone separating the general access zone from the restricted zone and having a slot extending therethrough.

**Dependent claims**

The dependent claims are related to particular embodiments of the system, blister pack and method defined in the independent claims.

**Conclusion**

Having regard to the observations set out above, it is clear that the subject-matter of claims 1 to 28 presently on file is novel, involves an inventive step and is capable of industrial applicability.

Accordingly, it appears that the present application meets the requirements of Article 33 (2), (3) and (4) PCT.

**Re Item VII**

**Certain defects in the international application**

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2 (b) PCT).

which both the general access zone and the restricted access zone of the blister are accessible. A child-resistant hinging cap is hingeably mounted to the tray, such that when the hinging cap is in a closed position it locks the blister pack in a first position and when the hinging cap is in an opened position it allows the blister pack to slide to a second position.

As used herein, the terms unit dose and pill includes pills, capsules, caplets, tablets, chewables, and similarly sized items that may suitably be stored in a blister pack. The term "restricted access" includes items that are secured in a child-resistant manner, and the term general access includes items that are not required to be secured in a child-resistant manner.

According to a first aspect of the present invention there is provided, a packaging system comprising a tray and a blister pack, the blister pack comprising a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot extending into said chamber-free zone, said general access zone and said restricted access zone being separated by said chamber-free zone; a blister retaining cap coupled to said tray for slideably securing said blister pack within said tray and a hinging cap hingedly mounted to said tray, said hinging cap controlling access to said restricted access zone, wherein the restricted access zone of the blister pack is capable of being slideably moved from a first position disposed below the retaining cap to a second position where access can be gained to the restricted access chambers.

3a

Preferably, the tray comprises a frame including end walls, sidewalls, and a mounting post attached to said frame.

More Preferably, the tray further include at least one general access window corresponding in position with said general access chambers, and at least one restricted access window corresponding in position with said restricted access chambers.

Preferably, each one of said plurality of general access chambers includes at least one general access item and each one of said plurality of restricted access chambers includes at least one restricted access item.

Preferably, the packaging system further comprises a central guide post extending through said guide slot.

Preferably, the blister retaining cap further includes a base and walls that form a hood, said hood covering the restricted access zone of said blister pack when said blister pack is in a first position.

Preferably, the tray further includes at least one stirrup formed within one of the side walls.

Preferably, the hinging cap includes a flap, and at least one button extending outwardly from a corresponding strut affixed to said flap.

3b

Preferably, the button correspondingly engages said stirrup so as to secure said hinging cap closed.

Preferably, the flap is hingeably fixed to said tray so that when said child-resistant hinging cap is in a closed position, said rib butts at least one of said restricted access chambers, locking the blister pack in the first position.

Preferably, the hinging cap is opened by inwardly deflecting said button so as to clear said stirrup, permitting said rib to clear said restricted access chambers and said blister pack to slide to a second position.

Preferably, the packaging system further including and outer sleeve configured to receive said tray, said blister pack, aid retaining cap, and said hinging cap.

Preferably, the outer sleeve includes a first open end and a second open end, such that when said tray is extended from first opened the child-resistant hinging cap is accessible, and when said tray is extended from said second end the general access zone is accessible.

Preferably, the tray, the retaining cap, and the child-resistant hinging cap comprise a plastic material.

Preferably, the access item comprises any one of a first medication, a second medication, a non-medication or any combination thereof.

3c

According to a second aspect of the present invention there is provided, for use in a packaging system, a blister pack comprising a general access zone including a plurality of general access chambers, each one of said general access chambers including at least one general access item, a restricted access zone including a plurality of restricted access chambers, each one of said restricted access chambers including at least one restricted access item and a chamber free zone including a guide slot, said general access zone and said restricted access zone being separated by said chamber free zone, wherein the blister pack is configured for co-operation with the packaging system such that the items in the general access zone are readily accessible but access to those items in the restricted access zone is restricted.

Preferably, the access items comprise of any one of a first medication, a second medication, a non-medication or any combination thereof.

Preferably, the blister pack further comprises a backing material affixed to the open side of said access chambers for securely enclosing said access items within said general access chambers and said restricted access items within said restricted access chambers.

According to a third aspect of the present invention there is provided, a method for packaging items, said method comprising packaging items in a blister pack, said blister pack including a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot axially extending into said chamber-free zone, said general access zone and said restricted access zone being

3d

separated by said chamber-free zone, loading said blister pack within a tray, affixing a retaining cap to said tray for slideably holding said blister pack within said tray and hingeably mounting a child-resistant cap to said tray for controlling access to said restricted access zone, wherein the restricted access zone of the blister pack is disposed in a first position below the retaining cap and is slideably moved from the first position to a second position where access can be gained to the restricted access chambers.

Preferably, the step of packaging includes placing at least one general access item into a corresponding general access chamber and placing at least one restricted access item into a corresponding restricted access chamber.

Preferably, the step of packaging further includes affixing a backing material to an open side of said chambers for securely enclosing said items.

Preferably, the step of loading includes inserting aid blister pack within said tray, said tray including a mounting post extending through the guide slot of said chamber-free zone.

Preferably, the step of affixing includes mounting blister retaining cap to said tray, said blister retaining cap including a central guide post that is coupled to said mounting post for allowing the blister pack to slide in a first position for accessing the general access zone and in a second position for accessing both the general access zone and restricted access zone.

Preferably, the step of affixing further includes positioning said retaining cap over the restricted access zone of said blister pack for covering said restricted access zone when the blister pack is in first said position.

Preferably, the step of hingeably mounting includes hingeably attaching said hinging cap to said tray, placing said hinging cap in a closed position that a holding rib positioned within aid hinging cap butts against at least one of said restricted access chambers thereby locking the blister pack in said first position and preventing the blister pack from sliding in said second position, and placing said hinging cap in an open position so that said rib clears restricted access chamber allowing the blister pack to slide into the second position for gaining access to the restricted access zone.

Preferably, the method further includes slideably inserting said tray, said blister pack, said retaining cap and said hinging cap within an outer sleeve, said outer sleeve including a first open end and a second open end.

Preferably the step of packaging includes placing at least one general access item comprising a first medication into a corresponding general access chamber and placing at least one restricted access item comprising a second medication into a corresponding restricted access chamber.

It is also contemplated that the present invention is not limited to pharmaceutical-related goods, but it is applicable to a plethora of delicate, sensitive, or unique portable goods. Small electronic components, jewelry, foods, inexpensive

4a

and precious articles, and any other item that requires a safe, stable and portable environment in which to be shipped and stored may find an application with the present invention. Other advantages of the present invention will be apparent from the following description, the accompanying drawings, and the appended claims.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIGS. 1 and 2 show exploded perspective views, from above and below, of an embodiment of the invention.

FIGS. 3-6 show a series of perspective views illustrating the operation of the hinging cap of FIGS. 1 and 2.

FIGS. 7-9 show a series of perspective views illustrating an alternative embodiment of the present invention.

**DETAILED DESCRIPTION**

As required, embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The figures are not

- 14 -

## CLAIMS

1. A packaging system comprising a tray and a blister pack, the blister pack comprising a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot extending into said chamber-free zone, said general access zone and said restricted access zone being separated by said chamber-free zone; a blister retaining cap coupled to said tray for slideably securing said blister pack within said tray and a hinging cap hingedly mounted to said tray, said hinging cap controlling access to said restricted access zone, wherein the restricted access zone of the blister pack is capable of being slideably moved from a first position disposed below the retaining cap to a second position where access can be gained to the restricted access chambers.
- 10 2. The packaging system of claim 1, wherein said tray comprises a frame including end walls, sidewalls, and a mounting post attached to said frame.
- 15 3. The packaging system of claim 2, wherein said tray further includes at least one general access window corresponding in position with said general access chambers, and at least one restricted access window corresponding in position with said restricted access chambers.
- 20 4. The packaging system of claim 3, wherein each one of said plurality of general access chambers includes at least one general access item and each one of said plurality of restricted access chambers includes at least one restricted access item.
- 25 5. The packaging system of claim 4, further comprising a central guide post extending through said guide slot.
- 30 6. The packaging system of claim 5, wherein said blister retaining cap further includes a base and walls that form a hood, said hood covering the restricted access zone of said blister pack when said blister pack is in a first position.

Amended claims

- 15 -

7. The packaging system of claim 6, wherein said tray further includes at least one stirrup formed within one of side walls.

8. The packaging system of claim 7, wherein said hinging cap includes a flap, 5 and at least one button extending outwardly from a corresponding strut affixed to said flap.

9. The packaging system of claim 8, wherein said button correspondingly engages said stirrup so as to secure said hinging cap closed.

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10. The packaging system of claim 9, wherein said flap is hingeably fixed to said tray so that when said child-resistant hinging cap is in a closed position, said rib butts at least one of said restricted access chambers, locking the blister pack in the first position.

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11. The packaging system of claim 10, wherein said hinging cap is opened by inwardly deflecting said button so as to clear said stirrup, permitting said rib to clear said restricted access chambers and said blister pack to slide to a second position.

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12. The packaging system of claim 11, wherein said blister retaining cap further includes a semicircular well.

13. The packaging system of claim 1, further including an outer sleeve configured to receive said tray, said blister pack, said retaining cap, and said hinging cap.

25

14. The packaging system of claim 13, wherein said outer sleeve includes a first open end and a second open end, such that when said tray is extended from said first open end the child-resistant hinging cap is accessible, and when said tray is extended from said second end the general access zone is accessible.

30

15. The packaging system of claim 1, wherein said tray, said retaining cap, and said child-resistant hinging cap comprise a plastic material.

- 16 -

16. The packaging system of claim 4, wherein said access item comprises any one of a first medication, a second medication, a non-medication or any combination thereof.

5 17. A blister pack for use in a packaging system of claim 1, the blister pack comprising a general access zone including a plurality of general access chambers, each one of said general access chambers including at least one general access item, a restricted access zone including a plurality of restricted access chambers, each one of said restricted access chambers including at least one restricted access item and a chamber free zone including a guide slot, said general access zone and said restricted access zone being separated by said chamber free zone, wherein the blister pack is configured for co-operation with the packaging system such that the items in the general access zone are readily accessible but access to those items in the restricted access zone is restricted.

15 18. The blister pack of claim 17, wherein said access items comprise any one of a first medication, a second medication, a non-medication or any combination thereof.

19. The blister pack of claim 18, further comprising a backing material affixed to the open side of said access chambers for securely enclosing said general access items within said general access chambers and said restricted access items within said restricted access chambers.

20. A method for packaging items, said method comprising:

25 packaging items in a blister pack, said blister pack including a general access zone including a plurality of general access chambers, a restricted access zone including a plurality of restricted access chambers, and a chamber-free zone including a guide slot axially extending into said chamber-free zone, said general access zone and said restricted access zone being separated by said chamber-free zone; wherein  
30 in use access to the restricted access zone of the blister pack is restricted when the restricted access zone is disposed in a first position below the retaining cap and access may be guided to the restricted access chambers by slideably moving the blister pack from the first position to a second position where the restricted access zone is accessible;

Amended claims

- 17 -

loading said blister pack within a tray;  
affixing a retaining cap to said tray for slideably holding said blister pack  
within said tray; and,  
hingeably mounting a child-resistant cap to said tray for controlling access to  
said restricted access zone.

5 21. The method of claim 20, wherein said step of packaging includes placing at  
least one general access item into a corresponding general access chamber and placing  
at least one restricted access item into a corresponding restricted access chamber.

10 22. The method of claim 21, wherein said step of packaging further includes  
affixing a backing material to an open side of said chambers for securely enclosing  
said items.

15 23. The method of claim 22, wherein said step of loading includes inserting said  
blister pack within said tray, said tray including a mounting post extending through  
the guide slot of said chamber-free zone.

20 24. The method of claim 23, wherein said step of affixing includes a mounting  
blister retaining cap to said tray, said blister retaining cap including a central guide  
post that is coupled to said mounting post for allowing the blister pack to slide in a  
first position for accessing the general access zone and in a second position for  
accessing both the general access zone and the restricted access zone.

25 25. The method of claim 24, wherein said step of affixing further includes  
positioning said retaining cap over the restricted access zone of said blister pack for  
covering said restricted access zone when the blister pack is in said first position.

30 26. The method of claim 25, wherein said step of hingeably mounting includes  
hingeably attaching said hinging cap to said tray, placing said hinging cap in a closed  
position so that a holding rib positioned within aid hinging cap butts against at least  
one of said restricted access chambers thereby locking the blister pack in said first  
position and preventing the blister pack from sliding in said second position, and  
placing said hinging cap in an open position so that said rib clears restricted access

- 18 -

chambers allowing the blister pack to slide into the second position for gaining access to the restricted access zone.

- 5 27. The method of claim 26, further including slideably inserting said tray, said blister pack, said retaining cap and said hinging cap within an outer sleeve, said outer sleeve including a first open end and a second open end.
- 10 28. The method of claim 21, wherein said step of packaging includes placing at least one general access item comprising a first medication into a corresponding general access chamber and placing at least one restricted access item comprising a second medication into a corresponding restricted access chamber.

Annotated claims